REMARKS

Amendments to the Claims

Reconsideration of this application is respectfully requested. Upon entry of the foregoing amendment, claims 16, 19-20, 26-33 and 37-49 are pending. Claims 16, 19-20, 26-29, 32-33 and 37 are currently amended, claims 17-18, 21-25, 34-36 are canceled and claims 38-49 are newly added.

Applicants respectfully request entry of the above amendment and submit that the above amendment does not constitute new matter. Support for amended claims 16, 19-20, 26-29, 32-33 and 37 and new claims 38-49 can be found throughout the specification and in the claims as originally filed. Support for new claims 38, 41 and 48 can be found, for example, at paragraphs [2], [14], [21] and [24] of the specification. Support for new claim 39 can be found, for example, at paragraphs [19] and [52]-[54] of the specification. Support for new claims 40 and 47 can be found, for example, at paragraphs [14], [21] and [56] of the specification. Support for new claim 42 can be found, for example, in claim 7 as originally filed. Support for new claim 43 can be found, for example, in claim 8 as originally filed. Support for new claims 44-46 can be found, for example, at paragraph [53] of the specification. Support for new claim 49 can be found, for example, in claim 5 as originally filed.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

Rejections Under 35 U.S.C. § 112, 1st Paragraph

A. Enablement

The Office Action states that claims 16-37 are rejected under 35 U.S.C. § 112, 1st paragraph. Applicants respectfully traverse the rejection and provide the following remarks.

The Office Action asserts that the specification does not reasonably provide enablement for a method of promoting growth or differentiation of hematopoietic stem cells or hematopoietic progenitor cells, said method comprising administering at least one promoter of growth or differentiation of hematopoietic stem cells or hematopoietic progenitor cells, wherein said at least one promoter contains Cofilin as an active ingredient. *See* pages 3 and 4 of the Office

Action. In particular, the Office Action alleges that the specification does not teach any variant, fragment or derivative of the Cofilin protein other than SEQ ID NO: 1. *See* page 5 of the Office Action. Furthermore, the Office Action alleges that although claims 22 and 24 have been amended to include hybridization conditions, these conditions encompass a broad range of hybridization temperatures, which may not remove the polynucleotide variants associated with non-specific hybridization. *See* page 7 of the Office Action.

Applicants have amended independent claims 16, 19 and 20 to recite that the at least one promoter comprising Cofilin includes "the amino acid sequence of SEQ ID NO: 1." Likewise, independent new claims 39 and 40 also recite that the at least one promoter comprising Cofilin includes the amino acid sequence of SEQ ID NO: 1. Furthermore, Claims 21-25 have been canceled. In light of these amendments, Applicants respectfully submit that the enablement rejection has been overcome.

The Office Action states that the specification is enabling for a method of promoting the growth of hematopoietic stem cells and hematopoietic progenitor cells *in vitro* or *ex vivo* comprising administering human non-muscle type Cofilin of SEQ ID NO: 1 (and optionally, one or more cytokines) to hematopoietic stem cells or hematopoietic progenitor cells *in vitro* or *ex vivo* to promote growth. *See* page 3 of the Office Action; *see also* page 11 of the Office Action ("the specification of the instant application discloses that human non-muscle type Cofilin of SEQ ID NO: 1 promotes the growth (proliferation) of hematopoietic stem cells and hematopoietic progenitor cells *in vitro/ex vivo*").

Applicants have amended independent claims 16, 19 and 20 to delete the recitation of "differentiation" and now relate to methods of promoting the growth of hematopoietic stem cells and hematopoietic progenitor cells comprising administering at least one promoter comprising Cofilin including SEQ ID NO: 1. In light of these amendments, Applicants respectfully submit the enablement rejection has been overcome.

The Office Action also states that the specification is enabling for a method of promoting the differentiation of hematopoietic stem cells and hematopoietic progenitor cells *in vitro* or *ex vivo* comprising administering human non-muscle type Cofilin of SEQ ID NO: 1 and one or more cytokines to hematopoietic stem cells and hematopoietic progenitor cells *in vitro* or *ex vivo* to promote differentiation. *See* page 3 of the Office Action.

Applicants have added new claims 39-49. These claims relate to methods of promoting the differentiation of hematopoietic stem cells and hematopoietic progenitor cells and a method of treating diseases that result from insufficient hematopoietic stem cells or hematopoietic progenitors. In addition, these claims include the step of administrating at least one promoter comprising Cofilin "including the amino acid sequence of SEQ ID NO: 1" and a cytokine other than Cofilin. Accordingly, Applicants respectfully submit that claims 39-49 are also enabled by the specification.

The Office Action asserts that the specification does not reasonably provide enablement for a method of treating a disease, regenerative medicine or expanding hematopoietic stem cells *ex vivo* by administering at least one promoter of growth or differentiation of hematopoietic stem cells, hematopoietic progenitor cells, or a combination thereof wherein said at least one promoter includes Cofilin as an active ingredient. *See* pages 3 and 4 of the Office Action. In particular, the Office Action alleges that the specification does not teach the administration of any Cofilin protein to any subject for the promotion of growth and differentiation of hematopoietic stem cells or progenitor cells. *See* page 9 of the Office Action.

Applicants have canceled claim 17. Claim 20 has been amended to delete the recitation of "regenerative medicine" and is now drawn to a method of treating diseases that result from insufficient growth of hematopoietic stem cells or hematopoietic progenitors comprising expanding hematopoietic stem cells or hematopoietic progenitors *ex vivo* by administering at least one promoter comprising Cofilin including the amino acid sequence of SEQ ID NO: 1 and transplanting the expanded hematopoietic stem cells or hematopoietic progenitors. Accordingly, claim 20 is not drawn to the administration of any Cofilin protein to any subject for the promotion of growth and differentiation of hematopoietic stem cells or progenitor cells. Rather, claim 20 is drawn to a method of treating comprising the steps of expanding cells *ex vivo* by administering at least one promoter of SEQ ID NO: 1 and then transplanting the expanded cells.

Applicants respectfully submit that one of ordinary skill in the art would readily appreciate that once the hematopoietic stem cells are expanded *ex vivo* following the administration of at least one promoter including SEQ ID NO: 1, the expanded cells may be transplanted and thus used in treating diseases that result from insufficient growth of hematopoietic stem cells or hematopoietic progenitor cells. Furthermore, methods of treating diseases by stem cell transplantation were known in the art that the time of filing the instant

application. In particular, at the time of the filing, autologous or allogeneic stem cell transplantation were well known in the art and extensively used as a basic means for ameliorating hematopoietic function. *See e.g.*, paragraph [5] of the specification. Accordingly, given the teachings of specification and the state of the art at the time of filing the instant application, Applicants respectfully assert that one of skill in the art would be able to perform the methods of the invention without undue experimentation.

In view of the above amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the enablement rejection.

B. Written Description

The Office Action states that claims 16-35 are rejected under 35 U.S.C. § 112, 1st paragraph, as failing to comply with the written description requirement. Applicants respectfully traverse the rejection and provide the following remarks.

The Office Action purports that the specification does not provide adequate written description of the clamed genus because the description of SEQ ID NO: 1 is not adequate written description of an entire genus of functionally equivalent polypeptides, which incorporate all variants, fragments and derivatives or an entire genus of methods of using variants, fragments and derivatives. *See* pages 14-15 of the Office Action. However, the Office Action indicates that methods of utilizing the human non-muscle type Cofilin of SEQ ID NO: 1 meet the written description provision of 35 U.S.C. § 112, first paragraph. *See* page 16 of the Office Action.

Applicants have amended independent claims 16, 19 and 20 to recite that Cofilin includes "the amino acid sequence depicted by SEQ ID NO: 1." Likewise, independent new claims 39 and 40 also recite that Cofilin includes the amino acid sequence of SEQ ID NO: 1.

In view of the above amendments, Applicants respectfully submit that the specification clearly provides adequate written description to demonstrate that Applicants were in possession of the claimed subject matter at the time of filing of the instant application. Accordingly, Applicants respectfully request reconsideration and withdrawal of the instant written description rejection.

Rejection Under 35 U.S.C. § 112, 2nd Paragraph

The Office Action states that claims 20 and 34 are rejected under 35 U.S.C. § 112, 2nd paragraph over the recitation of "regenerative medicine." Applicants have amended claims 20 and 34 to remove the term "regenerative medicine." In view of this amendment, Applicants respectfully request withdrawal of the rejection of claims 20 and 34 under 35 U.S.C. § 112, 2nd paragraph.

Conclusion

An indication of allowance of all claims is respectfully solicited. Early notification of a favorable consideration is respectfully requested.

Respectfully submitted,
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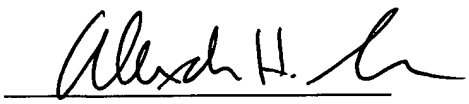
Dated: September 7, 2006 By: 

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